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## Preface

### 1. Welcome to this special issue of AJPS on inhalation drug delivery

On behalf of Inhalation Asia 2015 (IA15), we are delighted to bring to you this special issue on Inhalation Drug Delivery published by the *Asian Journal of Pharmaceutical Sciences*.

The special issue is published to coincide with the 2nd networking event of Inhalation Asia, the leading network of professionals in inhalation drug delivery in Asia ([www.inhalationasia.org](http://www.inhalationasia.org)). Inhalation Asia 2015 took place from 9 to 11 September 2015 at the Shenyang Pharmaceutical University in Shenyang, PR China.

### 2. Inhalation Asia 2015

This 2nd edition of Inhalation Asia hosted 150 delegates from East and West and fulfilled its ambition to connect scientists and technologists working on inhalation drug delivery in the Asian region and beyond.

The inhalation drug delivery community in the Austral-Asian regions is growing in numbers. New companies dedicating themselves to innovation in inhalation drug delivery start every month, and a number of academic centers are now well established in Shenyang, Beijing or Shanghai, Hong Kong, Taipei, Singapore, Otago, Tokyo, Seoul, Sydney, Melbourne, Mumbai. We were pleased to welcome many scientists and industrialists to the event.

### 3. IA15: a packed program

To our great pleasure, many of the world leading scientists in inhalation drug delivery accepted to present their recent research achievements and share their cutting-edge views. The program of IA15 was packed: from traditional lectures to discussions on early phase work during the poster sessions, the autumn school or the learn and brush-up of 2 workshop sessions. The program of IA15 was tailored to capture the particularity of the Asian inhalation world. Its focus and dynamics are different in some ways from the EU or US markets, yet call upon similar knowledge and technologies to achieve similar aims: improved therapies for lung disease. The 6 main sessions of IA15 covered the following topics: product devel-

opment, pharmaceutical sciences, e-cigarettes, lung cancer therapies, treatments for tuberculosis and how to bring finished products on different markets. All the posters and presentations of the event are available on our website at [www.inhalationasia.org](http://www.inhalationasia.org).

### 4. The AJPS special issue

Inhalation drug delivery in such a vast region as Asia is not at the same stage of development in every country. Japan's inhaled therapies are well established and driven mostly by brand products. All major pharmaceutical companies have inhaled products approved and on sale in Japan. Dry powder inhalers are particularly strong in Japan, with the world's only nasal dry powder inhaler being marketed there. Next in terms of maturity is India. There is a plethora of inhaled products manufactured and marketed in India. These are mostly generic products for the local market. India's expertise is primarily about APIs; finished products manufacturing stems from this expertise. Along with India, China is a well established supplier of APIs; what is lesser known to the outside world is that China has been fostering development in inhaled finished dosage forms for a couple of years, particularly with a view to effect the CFC to HFA transition for pMDI. Nebulisers are the preferred route of treatment for lung disease in China, but local pMDI products are being developed, and the CFDA is leading discussions on leachable and extractable in this context. DPIs are only in their infancy in China, at least for locally manufactured products, but China is known for the speed at which it embraces change, and local DPI products could well be ready sooner than is currently anticipated. Taiwan has manufacturing facilities for pMDIs and other inhaled products, alongside its API business. They are engaged mostly in generic products but have branded ambitions. Korea is a new starter in this field, local pharmaceutical companies are entering the market via generics but some already have brand pipelines. Singapore has been a hub for services to the pharmaceutical industry for a while, but no national champion has emerged yet for inhaled therapies, despite active academic centers. Malaysia is building up its respiratory industry: it is rumored that they are working in collaboration with Bangladesh, which has a generic industry with inhalation production facilities. Further afield in Asia, Turkey has world leading companies with inhaled marketed products. The inhalation industries in other very large countries such as Indonesia, Pakistan or the Philippines are

to this date inexistent or embryonic. The situation in the Middle East is more fluid and will be worth watching over the next few years.

The major limits to the expansion of inhalation industry in Asia are i) the maturity of market, ii) acceptance of the inhaled route as a viable route of medicine delivery, iii) lack of healthcare schemes, iv) the costs of medicines, v) lack of scientific ecosystems capable of innovation and problem solving, vi) inadequate quality assurance culture and implementation (let us not forget that in 2015 the EMA withdrew the marketing authorisations of 400 pharmaceutical products manufactured in India), and vii) a lack of a consistent and clear regulatory framework for medicine approvals in many of these markets. The lack of inhaled therapies is certainly not due to a lack of patients who would benefit greatly from treatments against asthma, COPD or tuberculosis.

In this special issue of AJPS we have tried to shed light on these many markets and their characteristics selected from the talks and posters presented at IA15. This special issue of AJPS on inhalation drug delivery is a snapshot of the talks and posters presented at IA15; 10 of the presenters were selected to publish their work in manuscripts that we are pleased to have gathered in this journal issue. The diversity of the topics in this special issue is a good testimony of the diversity of the inhalation field.

Parisini et al. in their modelling work demonstrate how the agglomeration process of blended particles can be fitted with classical equations; YongHong Liao et al. contribute to the understanding of HFA formulations with their work on particle surface morphology and pMDI performance; Bing Zhu et al. formulate theophylline as a DPI and evidence the efficacy of the formulation in vitro in cell models; Satu Lakio et al. prepare DPI formulations of amino acid L arginine and stress test them in very humid environment similar to those encountered in many Asian countries; HaoYing Li et al. prepare aztreonam-amino acid DPI formulations in the search for anti-tuberculosis therapies; the fight against tuberculosis is a very real concern in Asia, and Suresh et al. give another example of anti-tuberculosis therapies in their work with rifampicin lipospheres; e-cigarettes were invented in China, Cipolla et al. pick up on this topic on their paper on nicotine therapies; therapies against lung cancer are reviewed by WingHin Lee et al.; Shuguang Hou et al. give us an insight in the regulatory requirements for inhaled products across jurisdictions; Ducharme et al. challenge the status quo on inhaled bioequivalence studies with powerful arguments on bio markers is the necessity of PD studies.

We are most grateful to the authors and reviewers who gave their time and their talent to write articles of high quality and contribute to the debate on inhaled therapies.

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## 5. Inhalation Asia is more than a conference

Inhalation Asia is an open community of scientists and practitioners; it is a unique opportunity for all of us to meet in person, network with each other and showcase our ideas, research, products, and materials.

Inhalation Asia lives beyond its 3 day event every 2 years. You can follow us on our website, on LinkedIn, on Twitter and WeChat. Thanks to all of your efforts, support and creativity, we have been able to federate a lively online community, making Inhalation Asia more active and fun every day.

Inhalation Asia is committed to open access to the conference materials, abstracts, lectures and posters. All practitioners in the field of inhalation drug delivery can access the conference materials as long as they are registered users on the IA website ([www.inhalationasia.org](http://www.inhalationasia.org)). AJPS is also an open-access journal, and we are pleased to be associated with them.

We hope you will enjoy this special issue we edited.

The guest editorial team.

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